In re Patent Application of: Gueller et al.

Serial No.: 10/381,555

## REMARKS

In response to the office action mailed March 26, 2008, Applicant has withdrawn claims 17-36 and has elected to proceed with claim 1-6, in confirmation to the provisional election previously made in a telephone conference.

Regarding the rejection of Claims 1 to 16 under 35 USC § 102(b) as being anticipated by Nakashio et al (US 3,997,703), the Applicant has noted the Office Action's position. The Applicant has accordingly studied Nakashio et al on a careful word-for-word basis, but has come to the considered conclusion that the Office Action's views in this regard are not well founded. The Applicant's reasons for its position are set forth in detail hereunder.

- 1. The Applicant's view is based on the fact that Claim 1 of the present application is limited explicitly to different chemical species which are complementary, in that they are physically bonded together by interpolymer complexation to form an interpenetrating physical network. It is thus to be emphasized that there is not only interpolymer complexation, but that this complexation is defined to be physical in nature.
- Interpolymer complexes and their properties are well known in the art of polymer chemistry. By way of background, the Applicant annexes representative reviews and monographs on interpolymer complexation, namely:

Bekturov *et al*, Adv. Polym. Sci., 41, 99 (1981); Tsuchida *et al*, Adv. Polym. Sci., 45.1 (1982); and

Jiang et al, Adv. Polym. Sci., 146, 121 (1999)

With regard to the above-listed monographs and reviews (copies of which are included herewith), they demonstrate explicitly, fully and indeed extensively that the phenomenon of interpolymer complexation has been known to persons skilled in the art, i.e. to polymer chemists, for decades, and should therefore be given full weight and credence. It is to be emphasized that the documents listed above are merely a selection from numerous publications

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in the art of interpolymer complexation, selected by virtue of their being reviews and/or monographs dealing more or less extensively and comprehensively with the subject in general terms.

- 3. It is further to be emphasized, with particular reference to the sentence bridging pages 2 and 3 of the present specification, that independent Claim 1, and hence all the remaining claims dependent thereon, use the terminology referring to interpolymer complexation in totally conventional fashion. This usage is consistent with the usage in the monographs/reviews listed in paragraph 2.3 above, with particular reference to Tsuchida et al at pages 5 10 thereof. In this regard a person skilled in the art knows that interpolymer complexation and macromolecular complexation are the same thing.
- 4. The above background is given to support the view that a polymer chemist of ordinary skill in the art would distinguish between those interpenetrating networks formed from different polar water-soluble polymeric species which are physically bound together, but are not complementary in the sense employed by the present specification so that interpenetrating networks constituted thereby are not interpolymer complexes, on the one hand, and those interpenetrating networks formed from different polar water-soluble polymeric species which are indeed physically bound together by virtue of their being complementary so that the interpenetrating networks formed therefrom are indeed interpolymer complexes, on the other hand. The polymer chemist of ordinary skill in the art would recognize and understand this distinction, and would find it to be perfectly clear. It is in the light of this background that the Applicant addresses the official action hereunder.
- 5. The Office Action indicates, at the bottom of page 7 running over to the top of page 5 of the official action, that Nakashio et al teaches that the barrier component comprises a polymeric layer comprising at least two different polymeric species which are polar and which are water-soluble, and having different chemical compositions and being complementary in that they are bound together physically by interpolymer complexation to form an interpenetrating

physical network. The Office Action refers in this regard to column 3 lines 62 to 68 of Nakashio et al. However, the passage in question to the contrary simply indicates that, in order to improve its (the moulded plastic) physical properties, the pullulan of the invention may be modified by esterification etc or may be blended with a water-soluble polymer such as polyvinyl alcohol. Thus, Nakashio et al does not disclose the formation of interpolymer complexes by using two complementary polymers; instead, it only provides a list of polymers that can be added to pullulan. Nowhere is there any mention of interpolymer complexes nor interpenetrating physical networks. Additionally, the polymers listed would not necessarily all be suitable as "complementary polymers" for interpolymer complex formation. The Office Action identifies a number of polymers from this list as examples of complementary species. namely "...polyvinyl alcohols, polyvinyl amines (this would appear to be in error since Nakashio et al does not disclose any polyvinylamines), polyvinyl imines (Nakashio et al discloses one polyvinylimine viz polyethyleneimine) and polyacrylamides...". However, these polymers, as well as pullulan, are all Lewis bases and thus they are not complementary in combination with pullulan in terms of interpolymer complex formation. Thus pullulan is unlikely to form interpolymer complexes of any significance with any of these polymers, and this is confirmed by Nakashio et al's own results/examples, where the oxygen barrier properties in fact worsened when polyvinyl alcohol (PVOH) was added to the pullulan - see also paragraph 8 hereunder.

- 6. For example, where Nakashio et al deal with pullulan/polyvinyl alcohol blends, there is neither an explicit nor an implied disclosure or hint/suggestion of interpolymer complexation, nor is there any suggestion that pullulan and polyvinyl alcohol are complementary in the fashion required by Claim 1. Furthermore, importantly, Nakashio et al do not provide even an inadvertent or accidental disclosure of interpolymer complexation, on any unknowing basis.
  - It follows that both pullulan and polyvinyl alcohol can interact with other

complementary polymer molecules having, for example, acid groups which interact with the alcohol groups of the pullulan or polyvinyl alcohol, but critically and it is submitted decisively, pullulan interacts no more strongly with polyvinyl alcohol than it does with itself, and, correspondingly, polyvinyl alcohol acts no more strongly with pullulan, than it does with itself. In other words, there is no more interpenetrating physical interaction in pullulan/polyvinyl alcohol blends, than there is between molecules of pure pullulan, or between molecules of pure polyvinyl alcohol. At best their interaction strengths are similar.

- 8. Once again critically and decisively, a proper reading of Nakashio *et al* shows that, if anything, there is less interaction between pullulan molecules, on the one hand, and polyvinyl alcohol molecules, on the other hand, than there is between pullulan molecules by themselves. In this regard the Examiner is respectfully directed to comparative Examples 1 and 2 of Nakashio *et al*. These Examples compare a barrier layer of pullulan by itself (Example 1), with a barrier layer of a mixture or blend of pullulan and polyvinyl alcohol (i.e. the precise blend relied upon by the Office Action under reply to show lack of novelty or anticipation). The significance of this is that pullulan, by itself, provides a barrier layer which is better and stronger, as a barrier, than the barrier layer provided by the pullulan/polyvinyl alcohol mixture/blend. Thus, Example 1 (pullulan) gives a permeation rate of  $10cc/m^2$ .day.atm (see Column 6, lines 55 56 of Nakashio *et al*), whereas Example 2 (pullulan/polyvinyl alcohol mixture/blend) gives a permeation rate which is double that of Example 1, being  $20cc/m^2$ .day.atm for Example 2.
- 9. The significance of the foregoing is that interpolymer complexation arises from polymer/polymer interactions which lead to tighter and better-ordered molecular packing with a reduction of intermolecular spaces, when compared with the complementary polymers which are the constitutents of the interpolymer complexes, by themselves. This leads to enhanced barrier properties of the interpolymer complexes which are higher or better than the barrier properties which would be predicted for mere mixtures/blends of the constituent complementary

polymers, bearing in mind the individual respective barrier properties thereof. Furthermore, the reduced intermolecular spaces are believed to be smaller than would be predicted for such mixtures/blends of the complementary polymers. Clearly, an increase in molecular packing tightness and a reduction in intermolecular spaces in a polymer, arising from interpolymer complexation and interaction between the complementary constituent polymers, results in reduced rates of gas or liquid permeation through a barrier layer formed therefrom, compared, for example, with the constituent polymers by themselves, or with a barrier layer formed from a polymer having the same molecular mass as the interpolymer complex but lacking the various complexation forces urging its molecules closely together to achieve more ordered packing, while reducing intermolecular spaces and reducing permeability (see Tsuchida et al at pages 6 – 10 for a summary of these forces).

10. To confirm the above, the Applicant has run comparative tests for its own situation, using polyvinyl alcohol by itself, methyl vinyl ether/maleic acid copolymer by itself, and the interpolymer complex formed from polyvinyl alcohol complexed with methyl vinyl ether/maleic acid copolymer. These permeability results are, using the parameters of the Example on pages 12 – 14 of the present specification:

polyvinyl alcohol by itself- 0.014 cm³/bottle/day; methyl vinyl ether/maleic acid copolymer by itself- 0.036 cm³/bottle/day; an interpolymer complex comprising 70% by mass polyvinyl alcohol and 30% by mass methyl vinyl ether/maleic acid copolymer- 0.003 cm³/bottle/day.

The interpolymer complex accordingly shows a dramatic reduction in permeability, compared with the individual constituent complementary polymers, which is a stark confirmation of the presence of interpolymer complexation. This improvement, being almost an order of magnitude, is fully consistent, when compared with the pullulan/polyvinyl alcohol blend of

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Nakashio et al, with the position that there is no interpolymer complexation in Nakashio et al whatsoever, whether accidental or inadvertent, or otherwise.

11. It is accordingly respectfully submitted that the Applicant has, in fully responsive fashion, shown that the Office Actions's prima facie view that Nakashio et al anticipates the claims presently on file, is not well founded.

It is respectfully submitted that the claims as amended are now in condition for allowance. A formal notice of allowance is earnestly solicited.

Applicant encloses herewith a petition of a three month extension of time as well as authorization for payment of the extension from deposit account number 230920. Applicant believes that no other fee is nor any other petition are needed; however, should it be determined that an additional fee is needed the Commissioner is authorized to charge any such fee to the above noted deposit account. Further, if an additional petition is required, Applicant respectfully requests that this paper be considered such petition and that the fee for such petition be charged to the above deposit account.

The Examiner is respectfully requested to contact the undersigned attorney upon entry of this amendment

Respectfully submitted,

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